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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/579,230	09/28/2006	Robert J. Veldman	BJS-620-439	1300

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EXAMINER	
HENRY, MICHAEL C	

ART UNIT	PAPER NUMBER
1623	

MAIL DATE	DELIVERY MODE
01/06/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/579,230	VELDMAN ET AL.	
	Examiner	Art Unit	
	MICHAEL C. HENRY	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 September 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *92-151* is/are pending in the application.

4a) Of the above claim(s) *147-151* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *92-124 and 127-146* is/are rejected.

7)☒ Claim(s) *125 and 126* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *05/12/06 & 10/05/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The following office action is a responsive to the Amendment filed, 09/23/09. Applicant's election without traverse of Group I in the reply filed on 09/23/09 is acknowledged.

Claims 147-151 withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 09/23/09.

The amendment filed 09/23/09affects the application 10/579,230 as follows:

1. Claims 92-146, the invention of Group I is prosecuted by the examiner.

   Claims are 147-151 are withdrawn.

2. The responsive is contained herein below.

Claims 92-151 are pending in application

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Information Disclosure Statement

The information disclosure statement filed complies with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609. It has been placed in the application file and the information referred to therein has been considered as to the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 122 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The terms "-$NHS(O)_2OH$) derivative" renders the claim indefinite. More specifically, in the absence of the specific derivatizations or distinct language to describe the structural modifications or the chemical names of the derivatized structure of this invention, the identity of said derivatives would be difficult to describe and the metes and bounds of said derivatives that applicant regard as the invention cannot be sufficiently determined because they have not been particularly pointed out or distinctly articulated in the claims. Therefore, the identity of this composition component is indefinite. Furthermore, the term " $NHS(O)_2OH$)derivative " is seen to be indefinite where applicant fails to provide how the structure or chemical moiety is modified to obtain some derivatized version which is intended to be an integral part of the composition claimed.

The term "topoisomerase II inhibitor" in claims 1,2,3,6,13,14,17, renders the claims indefinite. This term is not defined by the claims, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. More specifically, it is unclear which substance (s) constitutes a topoisomerase II inhibitor, especially in the absence of any indicated name, structure and/or form.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 92, 99, 100-105, 108-121 and 124 are rejected under 35 U.S.C. 102(b) as being anticipated by Slotte et al. (Biochemistry (1993), 32(31), 7886-92).

Claim 92 is drawn to a pharmaceutical formulation or comprising a drug and a short-chain sphingolipid having a given formula. Slotte et al. disclose applicant's composition comprising a sphingolipid of said given formula (LacCer) and a drug (cholesterol) (see abstract). Slotte et al. compound of the given formula has a Cas # 149930-50-7 (see abstract). Claims 99, 100-105, 108-121 and 124 are also anticipated by Slotte et al. since Slotte et al. composition comprising a sphingolipid of said given formula (LacCer) and a drug (cholesterol) wherein said sphingolipid has Cas # 149930-50-7 (see abstract).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 92-121, 135-146 are rejected under 35 U.S.C. 103(a) as being unpatentable over Higa et al. (US 5,936,076).

Claim 92 is drawn to a pharmaceutical formulation or comprising a drug and a short-chain sphingolipid having a given formula. Dependent Claims 93-121, 135-145 are drawn to said composition comprising specific compounds of the said formula and specific formulations of said composition. Claim 146 is drawn to a liposome containing said composition

Haga et al. disclose a compound having the given formula wherein R^1 is an O-linked saccharide (α-D-galactopyranosyl), R^2 is $-(CH_2)_6CH_3$ (i.e., C_7alkyl), R^3 is $-(CH_2)_{11}CH_3$ (i.e., C_{12}-alkyl), R^4 is -OH, R^N is –H and R^5 is -H (see compound 7 on Sheet 10, FIG. 6; see abstract and claim1; see also col. 1, line 65 to col. 2, line 49). Furthermore, Haga et al. disclose or suggest a subgenus having the given formula (see abstract and claim1; see also col. 1, line 65 to col. 2, line 49). In addition, Higa et al. disclose that the compounds have anti-tumor and immuno-stimulating activity.

The difference between applicants' claimed composition and the composition of Haga et al. is that applicants' composition also contains a drug.

It would have been obvious to one having ordinary skill in the art, at the time the claimed invention was made, in view of Higa et al., to prepare a composition comprising a combination of Haga et al.'s compound or any compound suggested by the subgenus of Higa et al. and an anti-tumor or anticancer drug such as doxorubicin to treat cancer or tumors, since the combination of compounds that are used to treat the same diseases are well known in the art. More specifically, it is obvious to combine individual compositions taught to have the same utility to form a new composition for the very same purpose. In re Kerkhoven, 626 F.2d 846, 205 U.S.P.Q. 1069 (C.C.P.A. 1980).

One having ordinary skill in the art would have been motivated in view of Haga et al. to prepare a composition comprising a combination of Haga et al.'s compound or any compound suggested by the subgenus of Haga et al. and an anti-tumor or anticancer drug such as doxorubicin to treat cancer or tumors, because a skilled artisan would reasonably be expected to prepare a composition comprising a combination of the compounds taught by Haga et al. and anticancer drug, to treat tumors or cancers based on type and/or severity of the tumor or cancer. It should be noted that claims 93-121, 135-146 which are limitations of claim 92 are also encompassed by this rejection as set forth above. It should also be noted that the preparation of different pharmaceutical formulations such as a liposomal formulation of active ingredients such said sphingolipid and antitumor drugs and excipients or adjuvants are common in the art and is well within the purview of a skilled artisan.

Claims 92, 99-121, 123 are rejected under 35 U.S.C. 103(a) as being unpatentable over Elias et al. (US 6,054,433).

Claim 92 is drawn to a pharmaceutical formulation or comprising a drug and a short-chain sphingolipid having a given formula. Dependent Claims 99-121, 123 are drawn to said composition comprising specific compounds of the said formula.

Elias et al. disclose that a composition comprising an inhibitor of β-glucosidase activity or β-glucocerebrosidase activity and a glycosphingolipid, particularly glucocerebroside can be used to stimulate epithelial cell proliferation and/or enhance epithelial moisturization and lubrication in a mammalian subject (see abstract and claims). Furthermore, Elias et al. disclose that the compounds N-acylglucosylsphingosine which includes N-octanoylglucosylsphingosine

and acylinojiritetrazoles, castanospermines and beta-xylosides can be used (see abstract and claims).

The difference between applicants' claimed composition and the composition of Elias et al. is that Elias et al. does not exemplify the use of a composition of a specific compound of the given formula in combination a drug, per se. However, Elais et al. disclose that compounds of the general formula and other compounds such as bromoconduritol-B-epoxide (a drug) can be used (see abstract and claim).

It would have been obvious to one having ordinary skill in the art, at the time the claimed invention was made, to prepare a composition comprising a combination of the inhibitors of such as N-octanoylglucosylsphingosine and bromoconduritol-B-epoxide to stimulate epithelial cell proliferation and/or enhance epithelial moisturization and lubrication in a mammalian subject, since Elias et al. disclose that the said compounds can be used and in addition the combination of compounds that are used to treat the same diseases are well known in the art. More specifically, it is obvious to combine individual compositions taught to have the same utility to form a new composition for the very same purpose. In re Kerkhoven, 626 F.2d 846, 205 U.S.P.Q. 1069 (C.C.P.A. 1980).

One having ordinary skill in the art would have been motivated in view of Elias et al. to prepare a composition comprising a combination of the inhibitors such as N-octanoylglucosylsphingosine and bromoconduritol-B-epoxide to stimulate epithelial cell proliferation and/or enhance epithelial moisturization and lubrication in a mammalian subject, since Elias et al. disclose that the said compounds can be used and based on factors such as type and/or severity of the condition and the type of subject to be treated .

Claims 92, 99-102, 105, 108-117 and 127-131, 135-146 are rejected under 35 U.S.C. 103(a) as being unpatentable over Futerman et al.(Methods in Enzymology (1992), 209(Phospholipid Biosynth.), 437-46).

Claim 92 is drawn to a pharmaceutical formulation or comprising a drug and a short-chain sphingolipid having a given formula. Dependent Claims 99-102, 105, 108-117 and 127-131, 135-146 are drawn to said composition comprising specific compounds of the said formula and specific formulations of said composition. Claim 146 is drawn to a liposome containing said composition

Futerman et al. disclose that a compound of the given formula which is a sphingolipid that bear a short-chain, radioactive fatty acid ([1-14C]hexanoic acid) can spontaneously transfer from either protein complexes or liposomes into biol. membranes without destroying membrane integrity and have proven particularly useful for studies of sphingolipid metabolism in tissue fractions (see abstract). Futerman et al.'s compound has a Cas# of 143152-77-6 (see abstract).

The difference between applicants' claimed composition and the composition of Furterman et al. is that applicant composition also contains a drug.

It would have been obvious to one having ordinary skill in the art, at the time the claimed invention was made, to prepare a composition comprising a combination of Futherman et al.'s compound and a drug such as a protein complex or liposome in order to use it to investigate or study the transfer of Futherman et al's compound from either protein complexes or liposomes into biological membranes without destroying membrane integrity and to study sphingolipid metabolism in tissue the sphingolipid metabolism in tissue.

One having ordinary skill in the art would have been motivated in view of Futerman et al. to prepare a composition comprising a combination of Futherman et al.'s compound and a drug such as a protein complex or liposome in order to use it to investigate or study the transfer of Futherman et al's compound from either protein complexes or liposomes into biological membranes without destroying membrane integrity and to study sphingolipid metabolism in tissue the sphingolipid metabolism in tissue. It should be noted that claims 99-102, 105, 108-117 and 127-131 which are limitations of claim 92 are also encompassed by this rejection as set forth above. It should also be noted that the preparation of different pharmaceutical formulations such as a liposomal formulation of active ingredients such said sphingolipid and antitumor drugs and excipients or adjuvants are common in the art and is well within the purview of a skilled artisan. Claims 125 and 126 are objected to as being dependent on a rejected claim

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Henry whose telephone number is 571-272-0652. The examiner can normally be reached on 8.30am-5pm; Mon-Fri. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Michael C. Henry
January 2, 2010.

/Shaojia Anna Jiang/
Supervisory Patent Examiner
Art Unit 1623